

Summary of New ISO 17025 Requirements (No Equivalent NELAC Sections)

5.4.1 Management requirements, Organization – Addresses conflicting interest, impartiality, and undue pressures for labs that are part of a larger organization that performs other activities. (ISO 17025 sections 4.1.4 and 4.1.5.e)

5.4.3 Document control – Requirement for procedures to control all documents that are part of the quality system including issues such as identification, review and approval, availability, revision or changes, and handling of obsolete documents. (ISO 17025 sections 4.3.1, 4.3.2.1, 4.3.2.2, 4.3.2.3, 4.3.3.1, 4.3.3.2, 4.3.3.3 and 4.3.3.4)

5.4.4 Review of requests, tenders and contracts – Requirement for policies and procedures for reviews, records of reviews to be maintained, and the process for amendments. (ISO 17025 sections 4.4.1, 4.4.2, 4.4.3, 4.4.4, and 4.4.5)

5.4.5 Subcontracting of environmental tests and calibrations (ISO 17025 section 4.5.3)

5.4.6 Purchasing services and supplies (ISO 17025 section 4.6.1)

5.4.7 Service to the client (ISO 17025 section 4.7)

5.4.9 Control of nonconforming environmental testing and/or calibration work – Requirement for policy and procedures, including corrective action procedures. (ISO 17025 sections 4.9.1 and 4.9.2)

5.4.10 Corrective action – Requirement for policy and procedures including cause analysis, selection and implementation, monitoring, and additional audits. (ISO 17025 sections 4.10.1, 4.10.2, 4.10.3, 4.10.4, and 4.10.5)

5.4.11 Preventive action – Definition and requirement for action plan development, implementation and monitoring, as needed. (ISO 17025 sections 4.11.1 and 4.11.2)

5.4.12 Control of records – Requirement to establish and maintain procedures for control of records addressing storage, security, electronic records, extent of records to be retained, and correction of mistakes. (ISO 17025 sections 4.12.1.1, 4.12.1.2, 4.12.1.3, 4.12.1.4, 4.12.2.1, 4.12.2.2, and 4.12.2.3)

5.4.13 Internal audits (ISO 17025 section 4.13.4)

5.5 Technical requirements, General and Personnel – Discussion of factors that determine reliability of environmental tests and requirement for policy and procedures to identify training needs and provide training to personnel. (ISO 17025 sections 5.1.1, 5.1.2, 5.2.2, and 5.2.3)

5.5.4 Environmental test and calibration methods and method validation – Requirements that labs **select methods** that meet the needs of the client, have plans for use of methods developed by the laboratory for its own use, and use non-standard methods only with agreement from the client. Definition and identification of the need for **validation of methods**. Requirement for procedures to estimate the **uncertainty of measurement**. (ISO 17025 sections 5.4.2, 5.4.3, 5.4.4, 5.4.5.1, 5.4.5.2, 5.4.5.3, 5.4.6.1, 5.4.6.2, and 5.4.6.3)

5.5.5 Equipment – Various specific requirements relating to equipment. (ISO 17025 sections 5.5.4, 5.5.5.c, 5.5.6, 5.5.9, 5.5.11, and 5.5.12)

5.5.6 Measurement traceability, Specific requirements – Requirement of a program to ensure the traceability of equipment and standards for calibration laboratories. Reference to calibration laboratory requirements for testing laboratories unless uncertainty from calibration contributes little to the total uncertainty of the test result. **(ISO 17025 sections 5.6.2.1.1, 5.6.2.1.2, and 5.6.2.2.1)**

5.5.6.3 Reference standards and reference materials – Requirements for intermediate checks and transport and storage. **(ISO 17025 sections 5.6.3.3 and 5.6.3.4)**

5.5.7 Sampling – Requirement that changes to sampling procedure be documented and communicated and that there are procedures for recording relevant sampling data and operations. **(ISO 17025: 5.7.2 and 5.7.3)**

5.5.8 Handling of samples – Requirement for procedures for the handling of samples including samples received in abnormal condition. **(ISO 17025 5.8.1 and 5.8.3)**

5.5.10.3 Test reports – Various additional required information to be included in test reports. **(ISO 17025 sections 5.10.3.1, 5.10.3.1.d, 5.10.3.1.e, and 5.10.3.2)**

5.5.10.4 Calibration certificates – Specific requirements for calibration certificates. **(ISO 17025 sections 5.10.4.1, 5.10.4.2, 5.10.4.3, and 5.10.4.4)**

5.5.10.5 Opinions and interpretations **(ISO 17025 section 5.10.5)**

5.5.10.8 Format of reports and certificates **(ISO 17025 section 5.10.8)**

5.5.10.9 Amendments to test reports and calibration certificates **(ISO 17025 section 5.10.9)**